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**(54) ACTIVATION TECHNIQUES FOR IMPLANTABLE MEDICAL DEVICE**

BETÄTIGUNGSTECHNIKEN FÜR MEDIZINISCHE IMPLANTIERBARE VORRICHTUNG  
TECHNIQUES D'ACTIVATION POUR DISPOSITIF MEDICAL IMPLANTABLE

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**EP 0 613 389 B1**

## Description

**[0001]** The present invention relates to a neurostimulator according to the preamble of claim 1. The invention refers generally to techniques and apparatus for activating implanted battery-operated neurostimulators for treating or controlling medical, psychiatric or neurological disorders by application of modulating electrical signals to a selected nerve or nerves of the patient.

**[0002]** Extra-physiologic electrical stimulation of the vagus nerve for treatment of epilepsy and various forms of involuntary movement disorders is disclosed in U.S. Patent 4,702,254 to J. Zabara, which discloses the features according to the preamble of claim 1 of the present invention. An implantable neurocybernetic prosthesis (NCP) utilizes neurocybernetic spectral discrimination by tuning the external current of the NCP generator to the electrochemical properties of a specific group of inhibitory nerves that affect the reticular system of the brain. These nerves are embedded within a bundle of other nerves, and are selectively activated directly or indirectly by the tuning of the NCP to augment states of brain neural discharge to control convulsions or seizures. According to the patent, the spectral discrimination analysis dictates that certain electrical parameters of the NCP pulse generator be selected based on the electrochemical properties of the nerves desired to be activated. An improved implantable neurostimulator has been proposed by the applicant. A block diagram of the stimulus generator of this neurostimulator is illustrated in Fig. 1, and further details of location of an implantable version of the device and the associated lead/electrode system are shown in FIG. 2. The implanted device communicates with a programmer and/or monitor external to the patient's body by means of asynchronous serial communication, to control and indicate device states.

**[0003]** Stimulus generator 10 is implanted in the body of a patient 30 in a surgically-formed pocket immediately beneath the skin in the chest (FIG. 2). Housing 21 is hermetically sealed and composed of a material biologically compatible with the fluids and tissue of the patient's body. The neurostimulator also includes implantable stimulating electrodes 25 together with a lead system 22 for applying the output signal of the stimulus generator to a selected nerve such as the patient's vagus nerve 27. Components external to the patient's body include a programming wand 33 for telemetry of parameter changes to the stimulus generator and monitoring signals from the generator, and a computer 35 and associated software for adjustment of parameters and control of communication between the generator, the programming wand and the computer.

**[0004]** The stimulus generator includes a battery 12, such as a lithium thionyl chloride cell, having terminals connected to the input of a voltage regulator 13. The regulator smoothes the battery output and supplies power to logic and control section 15, which includes a

microprocessor and controls the programmable functions of the device, such as current or voltage, frequency, pulse width, on-time and off-time of the output pulses generated by the generator. The programmability allows the output pulse signal to be selectively tailored for modulating the electrical activity of the vagus nerve to produce the treatment regimen applicable to the disorder. Timing signals for the logic and control functions of the generator are provided by a crystal oscillator 16. A magnetically-actuated reed switch 14 provides the capability for patient activation of the device.

**[0005]** Built-in antenna 17 enables communication between the implanted stimulus generator and the external electronics (including both programming and monitoring devices) to permit the device to receive programming signals for parameter changes, and to transmit telemetry information, from and to the programming wand. Once the system is programmed, it operates continuously at the programmed settings until they are reprogrammed (by the attending physician) by means of the external computer and the programming wand.

**[0006]** It is important to conserve energy in any battery operated device implanted for medical treatment of a disorder. To that end, a power down circuit 18 may be electrically connected to reed switch 14 and logic/control circuit 15 and timed by the clock pulses from the crystal oscillator 16 to reduce power to the microprocessor of section 15 and/or to the oscillator to a point at which the device is essentially in a sleep state but sufficiently alert to be awakened on command. The power down mode or sleep state may be initiated automatically within a timed interval after the device has been activated to generate its programmed stimulating output signal. Alternatively, the device may stay in a reduced power state until the microprocessor is awakened by manual activation of the device by the patient.

**[0007]** Logic/control section 15 of the stimulus generator 10 controls an output circuit 19 which generates programmed signal levels. The programmed output signal of section 19 is fed, via an electrical connector 20 on the generator case (housing) 21, to the lead assembly 22 which is connected at its distal end to the stimulating electrodes (FIG. 2). The parameters of the stimulating signal of the implanted device are calibrated by telemetry (via the programming wand 33) according to the patient's needs, and programmed into the microprocessor for delivery of treatment upon activation of the stimulus generator.

**[0008]** FIG. 2 illustrates the location of generator 10 in the patient's chest with nerve electrode array 25 and associated lead 22 implanted in the patient's neck. The lead is attached at its proximal end to connector 20 of housing 21. Electrode array 25 is a bipolar stimulating electrode, for example of the type described in U.S. Patent 4,573,481 to Bullara.

**[0009]** The implanted NCP of the above mentioned U.S. Patent 4,702,254 neurostimulator in the proposed improved stimulator is activated manually or automatically

to provide treatment for the duration of the seizure. The patient can manually activate the device by positioning a magnet over the implant site to actuate the reed switch at onset of the seizure. Automatic activation is triggered upon detection of instantaneous changes in certain state (EEG) parameters immediately before or at onset of a seizure. Also, a prophylactic or preventive mode may be employed in which the implanted device is activated periodically to reduce the occurrence and/or the intensity of the seizures.

**[0010]** It is a principal object of the present invention to provide improvements in techniques for manual and automatic activation of an implanted neurostimulator.

**[0011]** This object is achieved with the features of claim 1.

**[0012]** Rather than merely providing a magnet to be carried by the patient for manual activation of the implanted neurostimulator by applying the magnet to the external area immediately adjacent the implanted device, or adapting the device for automatic activation by periodic wakeups which are generated internally, the present invention recognizes that the availability of other or additional techniques for external control of device activation is desirable. A drawback of the current technique for manual activation, for example, is that the patient may have difficulty accessing the magnet quickly when onset of the disorder to be treated, such as an epileptic seizure, is sensed. On the other hand, specialized sensors such as EEG electrodes require complex and extremely delicate implantation procedures.

**[0013]** According to the present invention, apparatus for treating disorders by stimulation of a selected nerve or nerves of a patient includes, in addition to the implanted - stimulus generator and electrode array and associated lead, an activation means which is responsive to a patient initiated signal to activate, or in some instances to deactivate, the stimulus generator. According to one aspect of the invention, the neurostimulator is adapted to be activated to the "on" state in response to tapping by the patient on the skin overlying the implant site. In essence, the tapping produces vibrations or pressure on the generator housing, which is readily detectable. Various types of sensors may be incorporated in the device for this purpose.

**[0014]** In one embodiment, the sensor is an accelerometer or a piezoelectric element (ceramic or plastic) bonded or otherwise securely mounted to the inner surface of the housing of the device, preferably directly opposite the external surface of the housing which will underlie the skin after implantation. Such an element detects vibrations of or pressure changes on the housing, so that the light taps by the patient are sensed and the sense signal is used to activate the device.

**[0015]** Another embodiment includes programming the device to recognize a particular coded pattern or sequence of the taps so that, for example, if the device is currently in its stimulating state the coded sequence may be used to deactivate (turn off) the device or to in-

crease or decrease the output pulse amplitude and/or frequency. Alternatively or additionally, this capability is useful if the patient is about to perform some activity with which stimulation might interfere, by recognizing the patient's tapping sequence to delay stimulation by a pre-programmed time interval. Thus, the patient may be provided with a limited amount of control over the operation of the device, to an extent determined to be appropriate for the particular patient by the attending physician.

**[0016]** Automatic activation of the device by a patient-initiated signal is achieved according to the present invention by detecting an action by the patient which is indicative either of the onset or of the manifestation of the particular disorder to be treated. Thus, for example, although an imminent epileptic seizure may be detected by electrical measurements using implanted sensing (e. g., EEG) electrodes, implanted brain impedance measuring electrodes, or measurements of electrical activity of a peripheral nerve or the spinal cord, a much simpler technique for automatic activation which does not require additional implant surgery is to detect the violent movements by the patient which are characteristic of some types of seizures. The vibration sensor or accelerometer may also be used for that purpose. However, the sensitivity of the sensor must be made variable, as by programming, to permit it to be fine-tuned to the seizure characteristics of the specific patient. The desire is to assure that a seizure will be detected and the device activated to administer prompt treatment, but that the apparatus not be so sensitive that normal movements by the patient are sufficient to trigger nerve stimulation by the device.

**[0017]** Greater reliability of detecting violent motor activity which is characteristic of certain seizures may be achieved by locating the sensor on a limb of the patient, preferably in a bracelet to be worn on the patient's wrist. Alternative manual activation is also enhanced by incorporating a pushbutton which is readily depressed for electrical actuation of the implanted device when the patient senses a precursor or onset of the seizure. In this case, manual or automatic activation is triggered by use of miniaturized generator in the bracelet to transmit an audio or supersonic signal for detection by circuitry within the implanted neurostimulator. In one embodiment, the signal is detected by a piezoelectric device within the housing after being subjected to amplification and bandpass filtering.

**[0018]** Here also, the sensor, which is preferably located within the bracelet, may be an accelerometer, vibration sensor, or contact-type sensor such as mercury ball sensor in which the ball makes electrical connection with electrical contacts positioned about an internal enclosure when the patient's wrist undergoes movement. In the latter instance, the number of makes and breaks is indicative of the rapidity and violence of the movement.

**[0019]** Accordingly, a more specific object of the present invention is to provide means for manual and

automatic activation of an implanted neurostimulator in response to patient-initiated signals indicative of a need for treatment of a disorder by nerve stimulation.

**[0020]** Another object is to provide apparatus for activating a neurostimulator implanted in the body of a patient to respond to and treat epileptic seizures, in which the device is adapted to detect simple indicators of the disorder.

#### Brief Description of the Drawings

**[0021]** The above and still further objects, aspects, features and attendant advantages of the present invention will be better understood from a consideration of the ensuing detailed description of a presently preferred embodiment and method thereof, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a simplified block diagram of an implantable neurostimulator (stimulus generator portion), described above;

FIG. 2 is a simplified fragmentary illustration of the neurostimulator of FIG. 1 and related components implanted in the patient's body, also as described above;

FIG. 3 is a simplified block diagram of an embodiment of the circuitry incorporated in the stimulus generator housing for manual activation of the generator according to the present invention;

FIG. 4 is a block diagram of further details of the sensing circuit in the embodiment of FIG. 3;

FIG. 5 is a flow chart useful for explaining the operation of a portion of the embodiment of FIG. 3;

FIG. 6 is a simplified block diagram of another embodiment of a detection system for activating an implanted neurostimulator, both manually and automatically;

FIG. 7 is a pulse waveform generated by a portion of the circuit of FIG. 6;

FIG. 8 is an embodiment of a detection logic circuit for use in the circuit of FIG. 6;

FIG. 9 is an exemplary embodiment of a motion sensor for use in the circuit of FIG. 6;

FIG. 10 is a simplified block diagram of one embodiment of a detection system for use as part of the motion detection system in the circuit of FIG. 6; and  
FIG. 11 is a simplified block diagram of another embodiment of a detection system for use as part of the motion detection system in the circuit of FIG. 6.

#### Description of the Presently Preferred Embodiments

**[0022]** Referring to FIG. 3, an embodiment of the neurostimulator device for manual activation by the patient includes a piezoelectric sensor 50 in the form of a layer of polyvinylidene fluoride (PVDF, sold under the trademark "Kynar") or ceramic, sandwiched between and secured to a pair of electrically conductive layers 52, 53.

The piezoelectric sensor is bonded to the internal surface of housing 21 of the stimulus generator, opposite the external surface which will lie just beneath the skin of the patient after the device is implanted. It is desirable that the implantation procedure should produce good contact between that external surface of the housing and the tissue of the patient's body. All of the components of this embodiment which will permit manual activation are located within the stimulus generator housing.

**[0023]** A pair of electrically conductive leads 55, 56 connected to conductive layers 52, 53, respectively, are also connected to the input terminals of a sensing circuit 58 having externally programmable sensitivity. Further details of the sensing circuit are illustrated in FIG. 4. The electrical output of the piezoelectric sensor generated as a result of mechanical forces on the layer 50 produced by taps of the patient's finger on the skin overlying the implanted housing, are applied to sensing circuit 58 via leads 55, 56. This signal is applied to a charge amplifier 60 in the sensing circuit (FIG. 4), and the amplifier output is applied to a bandpass filter 62. The filter passes signal frequencies in the range from approximately 50 to 200 Hertz (Hz). The output signal from filter 62 is delivered to a detection circuit 63 adapted to produce an output in response to an input signal exceeding the preselected threshold level of detector 63. The sensitivity of sensing circuit 58 may be varied by appropriately programming the gain of amplifier 60 and/or the threshold level of detector 63, using the external programmer.

**[0024]** The sensing circuit 58 helps to assure that the device will not respond to extraneous vibrations imparted to the housing and to the piezoelectric sensor from sources (e.g., normal physical activities of the patient) other than taps by the patient intended to produce manual activation of the stimulus generator. This selectivity is enhanced by a timing and state circuit 65 (FIG. 3) to which the output signal (TAP) of sensing circuit 58 is applied. Circuit 65 also receives commands from the microprocessor 67 with associated random access memory (RAM) 68 within the logic and control section of the stimulus generator.

**[0025]** The operation of circuit 65 will be described by reference to the flow chart of FIG. 5. Implementation of a circuit and/or software to perform the functions of the timing and state circuit according to the flow chart of FIG. 5 can be achieved in a number of well known ways. The circuit is essentially a five state machine which waits in the ready state 69 for a tap sequence to begin. During the ready state a counter used to accumulate the number of taps in a sequence is held in the cleared state. Another counter which simply accumulates time since the last tap in a sequence is also held cleared.

**[0026]** Detection of a tap moves the state machine to the waiting state 70. The time counter begins running. This state serves to "debounce" the detection of a tap, which improves the chance that each tap is detected as a single event. On expiration of 100 milliseconds on the

time counter, for example, the state machine enters the increment state 71. In this state, the tap counter is incremented to register the detection of each individual tap. The state is exited upon occurrence of any of three different conditions.

**[0027]** If a tap occurs before either of the other two exit conditions, the counter which is counting time between taps is cleared (reset time out 72) and the machine then re-enters the waiting state 70. The other two conditions for exit from the increment state are detection of the maximum allowed count of taps, and elapse of the time-out period which is set, for example, to a value of about 1.5 seconds. If no further taps are detected during this time interval, the tap sequence is assumed to be over. Occurrence of either of the latter two exit conditions will cause an interrupt or flagging of the microprocessor (state 73) in the logic and control section.

**[0028]** The microprocessor reads the number of taps in the sequence (i.e., the tap count since the last reset), and acts upon the command represented by a sequence of taps of that number. When it is ready to receive new commands, the microprocessor resets the state machine to the ready state 69.

**[0029]** The most elementary commands are represented simply by numbers of taps counted. A one count may, for example, be treated as a probable accident, and ignored. On the other hand, a sequence of two or three taps may be used to trigger the output of a programmed burst from the output section by the microprocessor in the logic and control section. A sequence of four or five taps is used, for example, to turn off any burst in progress. Finally, a sequence of seven taps may be used to deactivate the device indefinitely, such as for an entire twenty-four hour period.

**[0030]** A more complex set of commands can be developed by additional use of the external magnet to activate the reed switch in the device. For example, a sequence of taps occurring while the reed switch is continuously closed may be used to encode the type of reprogramming requested. Any odd count may be ignored, while a count of two can be used to denote that the amplitude is to be decreased by a predetermined value, a count of four that the frequency is to be decreased by a set percentage, a count of six that amplitude is to be increased by a predetermined value, and a count of eight that the frequency is to be increased by a set percentage. These changes may be commenced immediately, or, if desired, may be delayed pending further refinement by elaborating input consisting of a tap sequence without closure of the reed switch within a specified time interval.

**[0031]** In this way, the implanted device is readily activated, controlled and may even be reprogrammed in appropriate cases by the patient by application of sequences of light taps on the skin overlying the implanted device. There is no need to carry a magnet or other obtrusive device for use in activating the neurostimulator, or to locate the magnet when it is needed for that purpose,

unless the magnet is to be used in combination with the taps for the more complicated commands. Also, the implanted device is readily programmed to recognize different coded patterns or sequences of taps by the patient, to do such things as turning off the device if it is currently in the stimulating mode, or to increase or decrease the intensity and/or frequency of the stimulation, or even to delay the initiation of stimulation for a selected time interval.

**[0032]** Another embodiment of the invention for convenient manual activation of the implanted neurostimulator by the patient, and which is also useful for automatic activation in the case of an epileptic or other patient whose seizures produce violent movements and are treatable by nerve stimulation, is depicted in FIG. 6. Part of the activation electronics are incorporated within a bracelet to be worn on the wrist of the patient. A wrist bracelet is a desirable location for two reasons. It is easily accessible by the patient for manual activation of the neurostimulator, and, in cases where the patient suffers from violent motor seizures, the positioning of a motion sensing device on a limb of the patient is more reliable for purposes of automatic activation.

**[0033]** In the embodiment of FIG. 6, the bracelet 75 (shown in fragmentary phantom lines) has incorporated therein a pushbutton switch 76, motion detection system 78, detection logic 80, and gated oscillator circuit 81. The electronics are readily fabricated in miniaturized form in a semiconductor integrated circuit. The power source for the device may be a battery such as a conventional watch-type battery, and preferably a lithium cell, which is of a size and capacity readily accommodated within the bracelet. Whether manually triggered by depressing the pushbutton switch or automatically triggered by a signal generated by the motion detector, the detection logic circuit 80 determines that the nature of its input signal is indicative of a need to activate the implanted neurostimulator. The logic circuit then provides an enabling input to gated oscillator 81 which produces a series of pulse trains each having a duration of about 50 milliseconds (ms) and a repetition rate (frequency) of about 10 kilohertz (Khz), with an off-time of 50 ms so that the cycle of consecutive trains is 100 ms, for example, as shown in FIG. 7.

**[0034]** Referring to the detailed detection logic illustrated in FIG. 8, such operation is triggered by either detected motion from a system 78 in the form of a logic true level from the X out of Y detector of FIG. 10 or a threshold detection from the circuit of FIG. 11 (both of which will be described in detail presently), or by manual closure of the activation pushbutton 76 on the bracelet, which causes a flip-flop 83 to be reset. This in turn activates gated oscillator 81 and starts the count of another time counter 84. When the latter counter overflows, such as at a count indicative of an elapsed time interval of 250 ms, the latch 83 is reset and the gated oscillator is shut off.

**[0035]** The gated oscillator output waveform is preferred,

erably of either audio frequency or ultrasonic frequency, for purposes of activating the neurostimulator. This output is applied to a ceramic piezoelectric transducer 82 such as that of the general type illustrated in FIG. 6, on the case of the wrist bracelet 75. The transducer is on the inside surface of the bracelet, in good contact with the patient's skin at the wrist. The purpose is to couple the sound signal produced directly into the arm through the transducer, so that transmission proceeds directly through the bulk of the limb into the trunk, where it is received by a transducer (not shown) affixed to the inside surface of the case of the implanted stimulus generator. The signal may be boosted to detectable levels by use of a tuned amplifier within the stimulus generator case. A characteristic 50 ms on / 50 ms off pattern is detected to maximize noise immunity, with three "on" phases separated by two "off" phases providing a reasonable key.

**[0036]** The tuned amplifier acts as a high Q filter centered near or at the highest frequency (e.g., 10KHz). The receiving system is adapted to look for alternating on and off periods at the correct repetition rate (here, 10 Hz; i.e., bursts of 10KHz repeat at a 10 Hz rate). These safeguards are intended to assure that the neurostimulator is activated or otherwise controlled (such as to increase the intensity or frequency of the stimulation, deactivate the device or delay the stimulation) only by the appropriate signal, and not by false signals.

**[0037]** A motion sensor is provided within the bracelet for automatically detecting movements by the patient. The motion sensor portion of the detection system 78 (FIG. 6) may be of any known type, such as an accelerometer or a vibration sensor, but preferably, is a contact-type sensor as shown in principal part in FIG. 9. A conductive ball such as a mercury ball makes electrical connection between adjacent electrical contacts positioned about an otherwise electrically insulative enclosure when the patient's wrist undergoes movement. In the contact-type sensor, the number of makes and breaks and specific location of the contacts is indicative of the rapidity and violence of the patient's movements at the wrist location.

**[0038]** As shown in FIG. 9(a) and (b), which are top and side views, respectively, of the interior of such a contact-type sensor, an electrically insulative wall (floor) 85 of the enclosure 88 on which the rolling mercury ball 86 moves is covered with spaced-apart electrical contact posts or pins (electrodes) 87. The spacing between the pins is just less than the width of the ball 86 resting on the floor surface, so that adjacent electrodes will be shorted by the ball when it encounters them. Alternate ones of the pins are grounded, as indicated by the dark circles in FIG. 9(a), and the others are used for sensing.

**[0039]** Motion of the patient's wrist causes the ball 86 to move about surface 85, and in the process to bridge adjacent pairs of the pins 87. Each sensing pin is passively pulled up to the positive supply. The sensor output is applied to an X of Y detection system such as that

shown in FIG. 10, as the processing portion of the motion detection system.

**[0040]** The circuit of FIG. 10 operates as follows. A flip-flop 95 associated with each pin, such as 93, stores the state of the input at the time of last sampling. An exclusive-OR function 96 compares the stored value with the current value, and, if the two differ, produces a logic true output. The outputs of all of the pin monitoring circuits are OR'ed together by OR gate 98 at the set input of a set/reset flip-flop 100. If the logic state of any pin changes while this flip-flop is not being reset, the presence of a state change is recorded. Once in each clock period 101 (for example, nominally each 40 ms) this information is shifted into a register 102 which has a bit representing the presence of an input state transition for each of the latest N clock periods. The parallel outputs of the shift register are monitored by an X of Y detector 105 and, if a high enough percentage (X of Y) show state changes, this constitutes recognition that motion of the type to cause triggering of activation has been detected.

**[0041]** The same clock edge that clocks the logic level of the set/reset flip-flop 100 into the register 102 clocks the current state of the input pin into flip-flop 95 which stores the last value. The phase of the clock which begins with this edge resets the set/reset flip-flop to a zero level. This clock phase is preferably shorter than the complementary phase to maximize the percentage of time during which the system is sensitive to state changes.

**[0042]** If vigorous motion occurs, the conductive ball will roll around and make contact in rather random fashion with pairs of pins. The more vigorous the motion, the higher the percentage of time that different pins will be affected, and the higher the probability that a pin state transition will be detected during any given sampling interval. This, in turn, increases the probability that the X of Y detector will detect an event.

**[0043]** The X of Y detector may be implemented in hardware or software. In a hardware implementation, the length of the shift register is  $Y + 1$ . A running count of the number of 1's in the first Y bits is maintained using an accumulator and an adder. Each time a new state enters the shift register, a comparison is made with the oldest bit. If the oldest bit in the register is the same as the newest bit, the value in the accumulator remains unchanged. If the oldest bit is different, the accumulator is either incremented (when the newest bit is a 1 and the oldest bit a 0), or decremented (when the newest bit is a 0 and the oldest bit a 1). If the accumulator reaches the threshold, then seizure detection is declared and the stimulus generator is activated to generate its treatment.

**[0044]** If motion is detected using an accelerometer, a threshold detection system such as that shown in FIG. 11 may be used as the processing portion of the motion detection system, to trigger activation of the stimulus generator. FIG. 11(a) is exemplary of the use of a one-dimensional accelerometer (not the mercury ball con-

tact sensor described above) to sense motion. In this case, the acceleration signal is subjected to bandpass filtering in filter 112 followed by threshold detection by detector 113. Additional benefit can be derived in the signal processing function by an envelope detection followed by low pass filtering immediately before the threshold detection by detector 113, to reduce or eliminate responses to occasional brief but forceful accelerations arising from impact.

**[0045]** The more ideal case of three-dimensional motion sensing with threshold detection is illustrated in the circuit of FIG. 11(b). The signal from orthogonal accelerometers 120, 121, and 122 are bandpass filtered, rectified and combined, and the combination subjected to threshold detection, to provide a more realistic indication of forces on the bracelet of the type which should trigger the activation (or a more selective output) of the stimulus generator. If even greater accuracy were necessary, it could be provided by processing to calculate the square root of the sum of the squares of the three acceleration signals.

**[0046]** While the motion detection system is shown as being implemented at least in part external to the patient's body, which is preferred because of the greater reliability of detection of violent movements associated with certain seizures, the motion detection system may instead be incorporated within the housing of the implanted stimulus generator, or be implanted in the patient's body within its own separate case.

**[0047]** In the context of the disclosure and the claims, the terminology "signal initiated by the patient" or "patient initiated signal" is intended to mean and refer to signals which are manually produced by the patient by means which are part of or worn by the patient (in contrast to the requirement of a separate device such as a magnet), or to signals which are automatically produced as a result of an external manifestation of the disorder by the patient (in contrast to an internal parameter such as EEG changes).

## Claims

1. Neurostimulator apparatus for treating and controlling a disorder of a patient susceptible to relief in response to therapy by predetermined modulation of the electrical activity of a selected cranial nerve of the patient, including a programmable stimulus generator (10) adapted for implantation into the body of the patient and including an electrode means (25) connectable to the stimulus generator and implantable in the body of the patient for electrical interaction with the selected nerve, so that the stimulus generator when activated will generate an electrical waveform which has been programmed with parameter values selected to stimulate the selected nerve by delivery via the electrode means to modulate the electrical activity of the selected nerve

in the predetermined manner to alleviate and control the disorder, wherein the apparatus includes an activation means (50 to 68; 75, 76, 80, 82) adapted to respond to a patient initiated signal which may be derived both manually and automatically for selectively activating the stimulus generator (10), the activation means including a motion sensor means (78, 85; 110, 120, 121) responsive to violent disorganized movements of the patient associated with a seizure of the patient for automatically activating the stimulus generator (10), **characterized in that** the activation means includes a detector (50, 58; 80, 82) responsive to tapping by the patient in at least one coded sequence of taps on the skin adjacent the implanted stimulus generator (10) for manual activation thereof.

2. The neurostimulator apparatus of claim 1, in which the activation means further includes an adjustment means (60, 67) for varying a preselected parameter of the therapy in response to another coded sequence of taps.
3. The neurostimulator apparatus of any of the preceding claims, in which the activation means further includes a deactivating means (65, 67) responsive to another coded sequence of taps while the stimulus generator (10) is activated for deactivating the electrode means.
4. The neurostimulator apparatus of any of the preceding claims, in which the activation means further includes a delay means (65, 67) responsive to a signal initiated by the patient for activating the stimulus generator (10) after a predetermined delay interval to cause the delivery of the therapy by the electrode means (82), when connected to the stimulus generator, to the selected body region and thereby to treat the disorder.
5. The neurostimulator apparatus of claim 1, in which the activation means includes sensitivity means (80) for determining the violence of the disorganized movements associated with a seizure of the patient.
6. The neurostimulator apparatus of claim 5, in which the motion sensor means (85, 110, 120, 121, 122) produces an electrical signal indicative of frequency of movements by the patient, and the sensitivity means includes an electrical signal filter (112) for limiting the electrical signal to a predetermined frequency band.
7. The neurostimulator apparatus of claim 6, in which the motion sensor means (85) produces an electrical signal indicative of the frequency of making and breaking of electrical contacts in response to move-

- ments by the patient, and the sensitivity means includes a counter (84) to ascertain the number of contacts made during a predetermined interval of the movements.
8. The neurostimulator apparatus of claim 1, in which the activation means comprises a device (75) adapted to be worn externally by the patient including manual signalling means (82) for producing a signal in the audio or ultrasonic frequency range.
  9. The neurostimulator apparatus of claim 8, in which the external device is a bracelet (75) which further includes sensing means (78) responsive to a physiological manifestation of the disorder being treated for producing a signal to automatically activate the stimulus generator.
  10. The neurostimulator apparatus of claim 9, in which the activation means further includes receiving means (80) located within a housing for the activation means and responsive to the signal produced by the sensing means (78) for ascertaining whether the signal is indicative of a physiological manifestation of the disorder being treated in contrast to a physiological manifestation of a normal reaction, and for limiting activation of the stimulus generator (81) in response to only a physiological manifestation of the disorder being treated.
  11. The neurostimulator apparatus of claim 10, further including means adapted to be located external to the patient for selectively adjusting the sensitivity of the receiving means to the signal produced by the sensing means.

#### Patentansprüche

1. Gerät zur Nervenstimulation zur Behandlung und Beherrschung einer Erkrankung eines Patienten, die einer Linderung durch eine Therapie in Form einer vorbestimmten Änderung der elektrischen Aktivität eines ausgewählten Hirnnervs des Patienten zugänglich ist, umfassend einen zur Implantierung in den Körper des Patienten vorgesehenen programmierbaren Stimulusgenerator (10) und eine an den Stimulusgenerator anschließbare Elektrode (25), die in den Körper des Patienten zur elektrischen Wechselwirkung mit dem ausgewählten Nerv eingesetzt werden kann, so dass, bei Aktivierung des Stimulusgenerators, dieser eine elektrische Wellenform erzeugt, die mit Parametern programmiert wurde, die so ausgewählt wurden, dass sie den ausgewählten Nerv über eine Elektrode stimulieren, um die elektrische Aktivität des ausgewählten Nervs in der vorbestimmten Weise zu verändern, um dadurch die Erkrankung zu lindern und

in den Griff zu bekommen, wobei das Gerät ein Aktivierungsmittel (50 bis 68; 75, 76, 80, 82) zur selektiven Aktivierung des Stimulusgenerators (10) umfasst, das auf ein vom Patienten erzeugtes und sowohl manuell als auch automatisch ableitbares Signal anspricht, wobei das Aktivierungsmittel einen Bewegungssensor (78, 85; 110, 120, 121) zur automatischen Aktivierung des Stimulusgenerators (10) umfasst, der auf die mit dem Greifen des Patienten verbundenen, heftigen, unkontrollierten Bewegungen des Patienten anspricht, **dadurch gekennzeichnet, dass** das Aktivierungsmittel einen Detektor (50, 58; 80, 82) umfasst, der auf ein in mindestens einer kodierten Abfolge von Klopfzeichen erfolgendes Klopfen des Patienten auf die Haut in der Nähe des implantierten Stimulusgenerators (10) zur manuellen Aktivierung desselben anspricht.

2. Gerät zur Nervenstimulation nach Anspruch 1, **dadurch gekennzeichnet, dass** das Aktivierungsmittel weiterhin ein Verstellmittel (60, 67) zur Änderung eines zuvor gewählten Therapieparameters umfasst, das auf eine weitere kodierte Abfolge von Klopfzeichen anspricht.
3. Gerät zur Nervenstimulation nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** das Aktivierungsmittel weiterhin ein Deaktivierungsmittel (65, 67) umfasst, das zur Deaktivierung der Elektrode bei aktiviertem Stimulusgenerator (10) auf eine weitere kodierte Abfolge von Klopfzeichen anspricht.
4. Gerät zur Nervenstimulation nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** das Aktivierungsmittel weiterhin ein Verzögerungsmittel (65, 67) umfasst, das auf ein vom Patienten ausgelöstes Signal zur Aktivierung des Stimulusgenerators (10) nach einem vorbestimmten Verzögerungsintervall, in dem die Elektrode (82), wenn sie an den Stimulusgenerator angeschlossen ist, die therapeutische Maßnahme in der gewählten Körperregion ausführt und somit die Erkrankung behandelt, anspricht.
5. Gerät zur Nervenstimulation nach Anspruch 1, **dadurch gekennzeichnet, dass** das Aktivierungsmittel empfindliche Mittel (80) zum Feststellen der Heftigkeit der mit dem Greifen des Patienten verbundenen, unkontrollierten Bewegungen umfasst.
6. Gerät zur Nervenstimulation nach Anspruch 5, **dadurch gekennzeichnet, dass** der Bewegungssensor (85, 110, 120, 121, 122) ein elektrisches Signal erzeugt, das die Bewegungsfrequenz des Patienten angibt und dass das empfindliche Mittel einen elektrischen Signalfilter (112) zur Begrenzung des



elektrischen Signals auf ein vorbestimmtes Frequenzband umfasst.

7. Gerät zur Nervenstimulation nach Anspruch 6, **dadurch gekennzeichnet, dass** der Bewegungssensor (85) ein elektrisches Signal erzeugt, das die Frequenz in der in Erwiderung auf Bewegungen des Patienten erfolgenden Bildung und Unterbrechung von elektrischen Kontakten angibt, und dass das empfindliche Mittel einen Zähler (84) zur Ermittlung der Anzahl der in einem vorbestimmten Bewegungsintervall gebildeten Kontakte umfasst.
8. Gerät zur Nervenstimulation nach Anspruch 1, **dadurch gekennzeichnet, dass** das Aktivierungsmittel eine Vorrichtung (75) aufweist, die dazu ausgebildet ist, äußerlich von dem Patienten getragen zu werden und ein manuelles Meldemittel (82) zur Erzeugung eines Signals im Ton- oder Ultraschall-Frequenzbereich umfasst.
9. Gerät zur Nervenstimulation nach Anspruch 8, **dadurch gekennzeichnet, dass** die externe Vorrichtung ein Armband (75) ist, das weiterhin Fühler (78) umfasst, die auf eine physiologische Manifestation der behandelten Erkrankung ansprechen, wodurch ein Signal erzeugt wird, das automatisch den Stimulusgenerator aktiviert.
10. Gerät zur Nervenstimulation nach Anspruch 9, **dadurch gekennzeichnet, dass** das Aktivierungsmittel weiterhin Empfangsmittel (80) umfasst, die in einem Gehäuse für die Aktivierungsmittel untergebracht sind und die auf das von dem Fühler (78) erzeugte Signal ansprechen, wobei diese Empfangsmittel dazu ausgebildet sind, zu ermitteln, ob das Signal auf eine physiologische Manifestation der behandelten Erkrankung im Gegensatz zu einer physiologischen Manifestation einer normalen Reaktion hinweist, und die Aktivierung des Stimulusgenerators (81) in Reaktion auf nur eine physiologische Manifestation der behandelten Erkrankung zu begrenzen.
11. Gerät zur Nervenstimulation nach Anspruch 10, **dadurch gekennzeichnet, dass** es weiterhin Mittel umfasst, die äußerlich an den Patienten angebracht werden und dazu ausgebildet sind, die Empfindlichkeit der Empfangsmittel selektiv auf das von dem Fühler erzeugte Signal einzustellen.

#### Revendications

1. Dispositif neurostimulateur pour traiter et contrôler une défaillance d'un patient à laquelle il peut être remédié en réponse à une thérapie par modulation prédéterminée de l'activité électrique d'un nerf crâ-

nien choisi du patient, comprenant un générateur de stimuli programmable (10) adapté à être implanté dans le corps du patient et comprenant un moyen d'électrode (25) connectable au générateur de stimuli et implantable dans le corps du patient pour interaction électrique avec le nerf choisi, de sorte que le générateur de stimuli, quand il est activé, produira une forme d'onde électrique qui a été programmée par des valeurs de paramètres choisies pour stimuler le nerf choisi par fourniture par le moyen d'électrode d'une modulation de l'activité électrique du nerf choisi de la façon prédéterminée pour remédier à la défaillance et la contrôler, dans lequel l'appareil comprend un moyen d'activation (50 à 68 ; 75, 76, 80, 82) adapté à répondre à un signal provoqué par le patient qui peut être obtenu manuellement et automatiquement pour activer sélectivement le générateur de stimuli (10), le moyen d'activation comprenant un moyen détecteur de mouvement (78, 85 ; 110, 120, 121) agissant en réponse à des mouvements violents et désorganisés du patient associés à une crise du patient pour activer automatiquement le générateur de stimuli (10), **caractérisé en ce que** le moyen d'activation comprend un détecteur (50, 58 ; 80, 82) agissant en réponse à un tapotement par le patient selon au moins une séquence codée de tapotements sur la peau près du générateur de stimuli implanté (10) pour son activation manuelle.

2. Dispositif neurostimulateur selon la revendication 1, dans lequel le moyen d'activation comprend en outre un moyen de réglage (60, 67) pour faire varier un paramètre prédéterminé de la thérapie en réponse à une autre séquence codée de tapotements.
3. Dispositif neurostimulateur selon l'une quelconque des revendications précédentes, dans lequel le moyen d'activation comprend en outre un moyen de désactivation (65, 67) agissant en réponse à une autre séquence codée de tapotements tandis que le générateur de stimuli (10) est activé pour désactiver le moyen d'électrode.
4. Dispositif neurostimulateur selon l'une quelconque des revendications précédentes, dans lequel le moyen d'activation comprend en outre un moyen de retard (65, 67) agissant en réponse à un signal provoqué par le patient pour activer le générateur de stimuli (10) après un intervalle de temps prédéterminé pour provoquer la fourniture de la thérapie par le moyen d'électrode (82), quand il est connecté au générateur de stimuli, à la région du corps choisie et traiter ainsi la défaillance.
5. Dispositif neurostimulateur selon la revendication 1, dans lequel le moyen d'activation comprend un moyen de sensibilité (80) pour déterminer la violence

ce des mouvements désorganisés associés à une crise du patient.

6. Dispositif neurostimulateur selon la revendication 5, dans lequel le moyen détecteur de mouvement (85, 110, 120, 121, 122) produit un signal électrique indicatif de la fréquence des mouvements du patient et le moyen de sensibilité comprend un filtre de signal électrique (112) pour limiter le signal électrique à une bande de fréquence prédéterminée. 5  
10
7. Dispositif neurostimulateur selon la revendication 6, dans lequel le moyen détecteur de mouvement (85) produit un signal électrique indicatif de la fréquence de l'établissement et de la rupture de contacts électriques en réponse à des déplacements du patient et le moyen de sensibilité comprend un compteur (84) pour confirmer le nombre de contacts effectués pendant un intervalle prédéterminé des mouvements. 15  
20
8. Dispositif neurostimulateur selon la revendication 1, dans lequel le moyen d'activation comprend un dispositif (75) adapté à être porté de façon externe par le patient, comprenant un moyen de signalisation manuelle (82) pour produire un signal dans la plage des fréquences audio ou ultra-sonores. 25
9. Dispositif neurostimulateur selon la revendication 8, dans lequel le dispositif externe est un bracelet (75) qui comprend en outre un moyen de détection (78) agissant en réponse à une manifestation physiologique de la défaillance traitée pour produire un signal pour activer automatiquement le générateur de stimuli. 30  
35
10. Dispositif neurostimulateur selon la revendication 9, dans lequel le moyen de détection comprend en outre un moyen de réception (80) disposé dans un boîtier pour le moyen d'activation et agissant en réponse au signal produit par le moyen de détection (78) pour confirmer que le signal est indicatif d'une manifestation physiologique de la défaillance traitée et non pas d'une manifestation physiologique d'une réaction normale et pour limiter l'activation du générateur de stimuli (81) en réponse seulement à une manifestation physiologique de la défaillance traitée. 40  
45
11. Dispositif neurostimulateur selon la revendication 10, comprenant en outre un moyen adapté à être disposé de façon externe sur le patient pour régler sélectivement la sensibilité des moyens de réception au signal produit par le moyen de détection. 50  
55

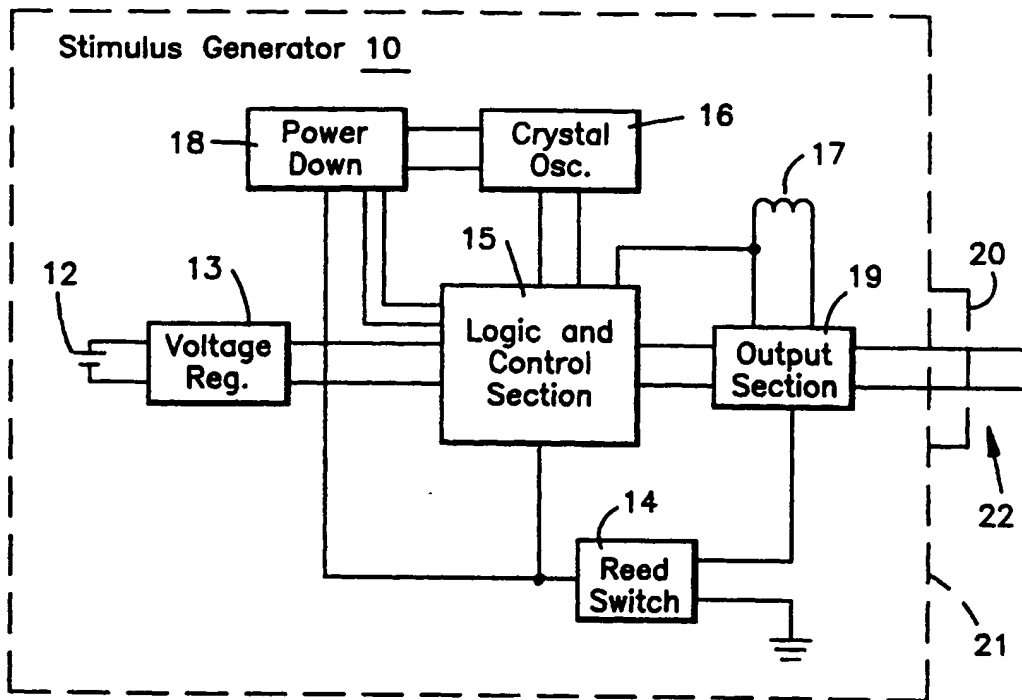


FIG. 1

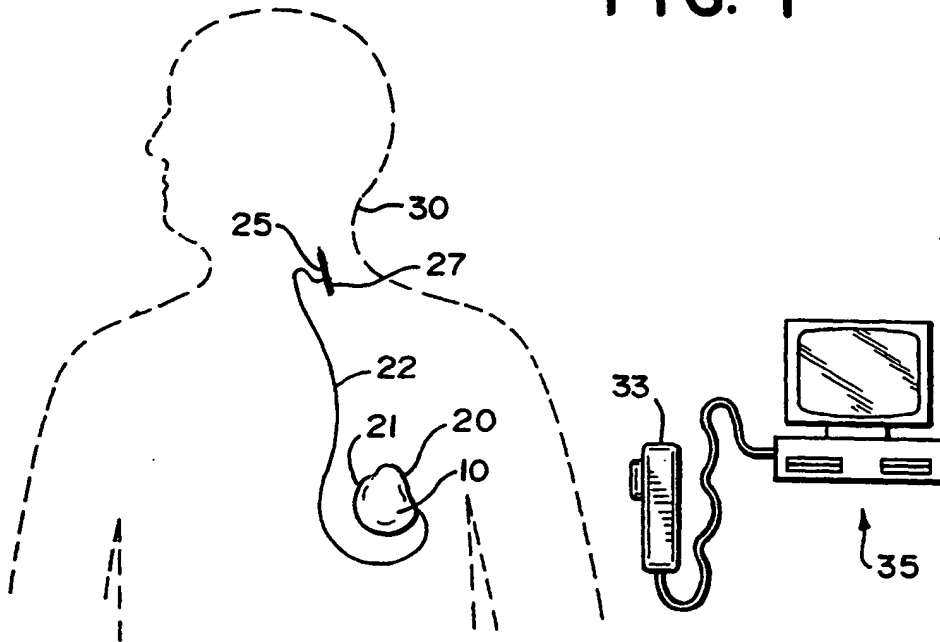
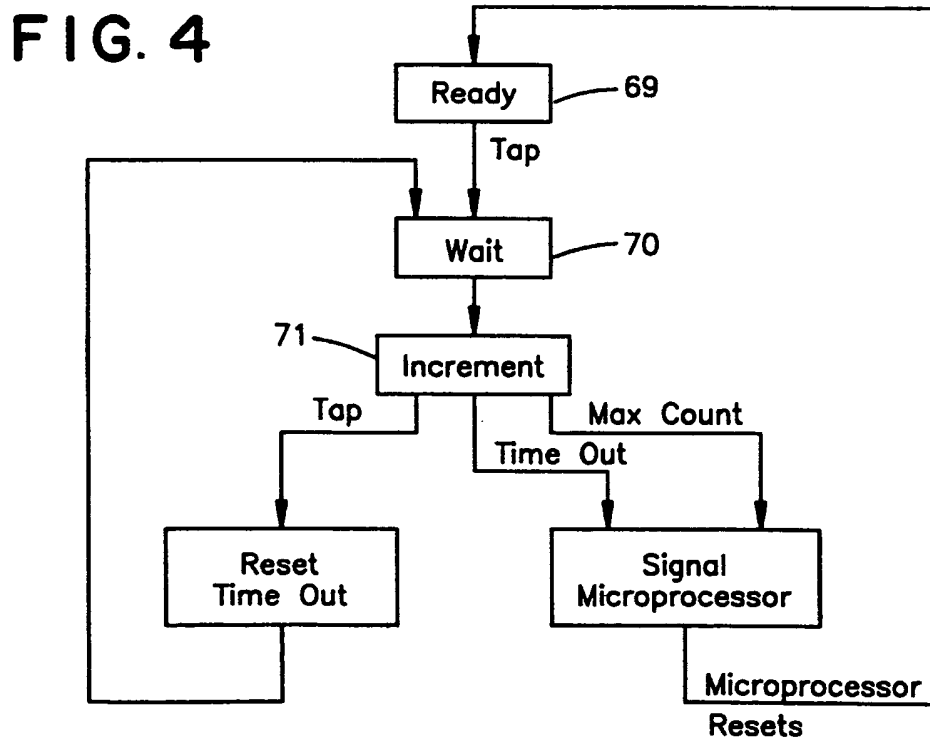
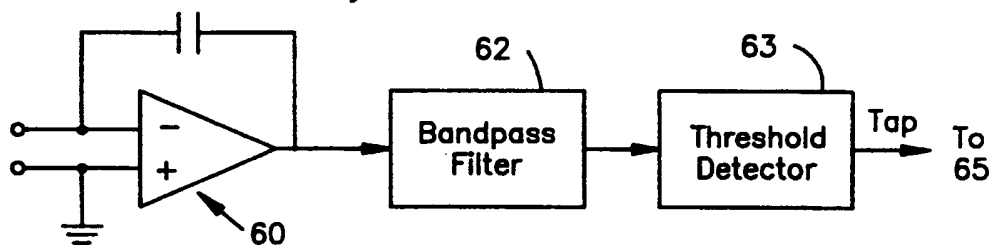
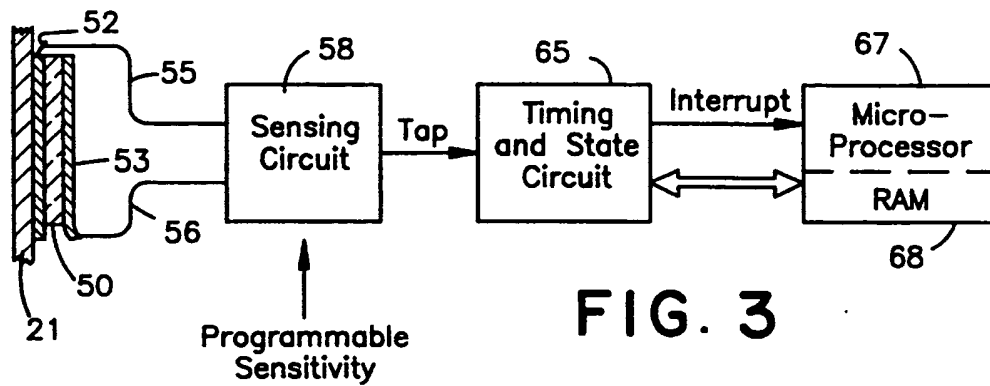
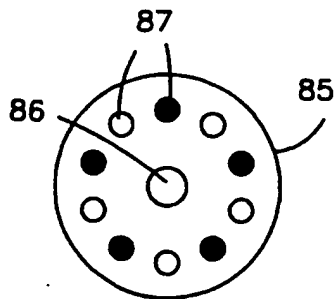
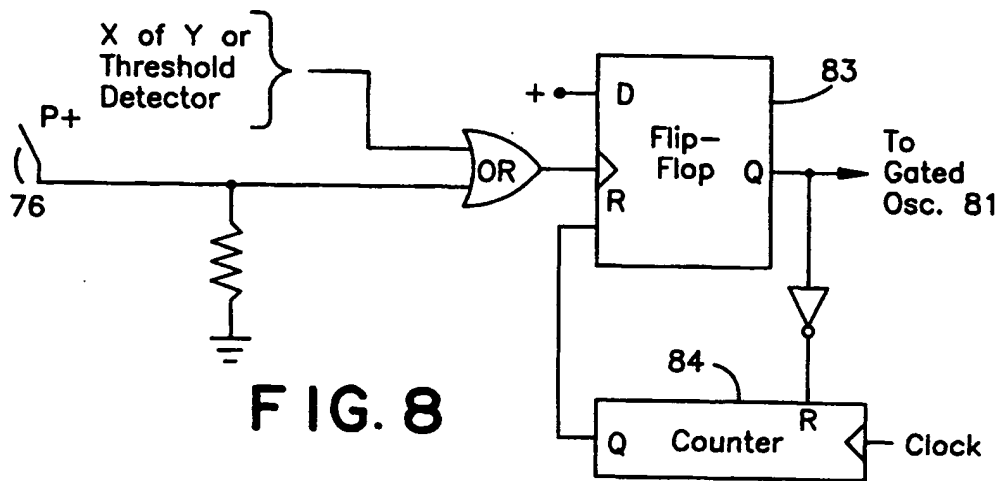
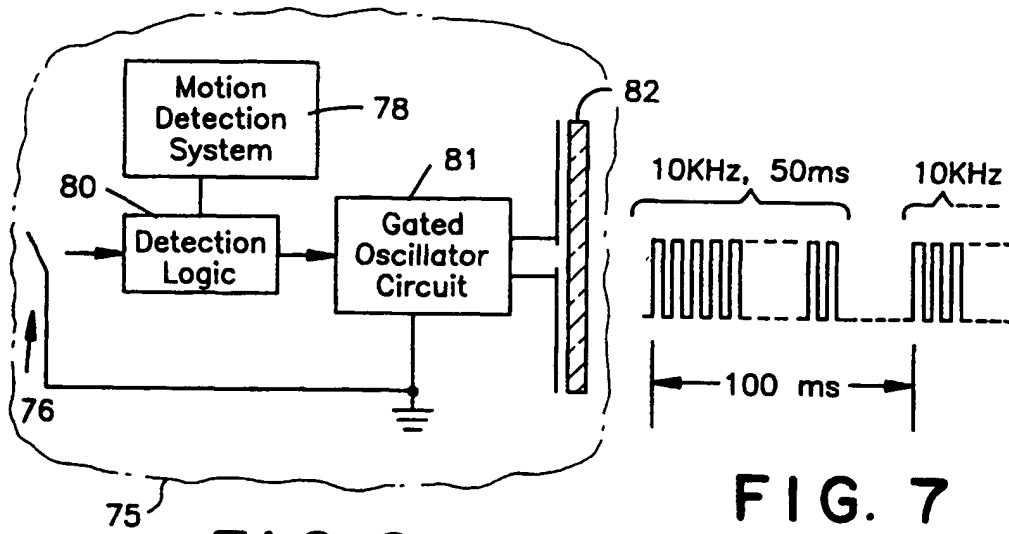
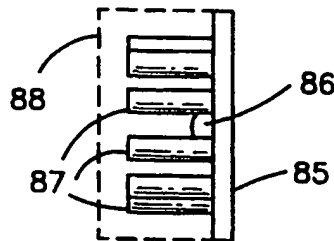


FIG. 2





**FIG. 9(a)**



**FIG. 9(b)**

FIG. 10

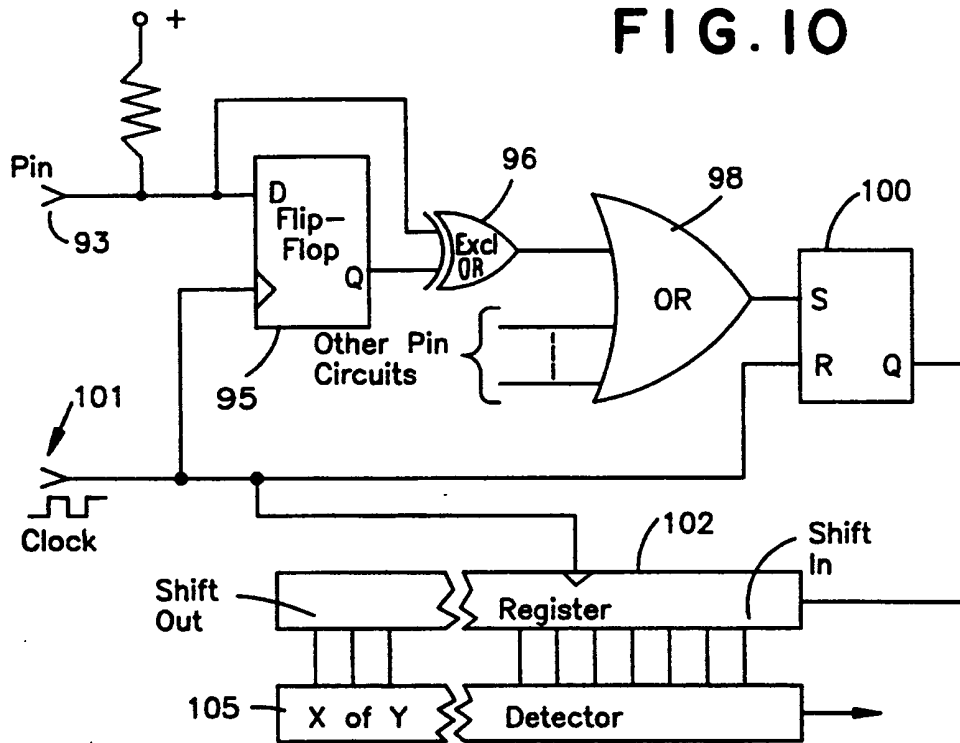


FIG. 11(a)

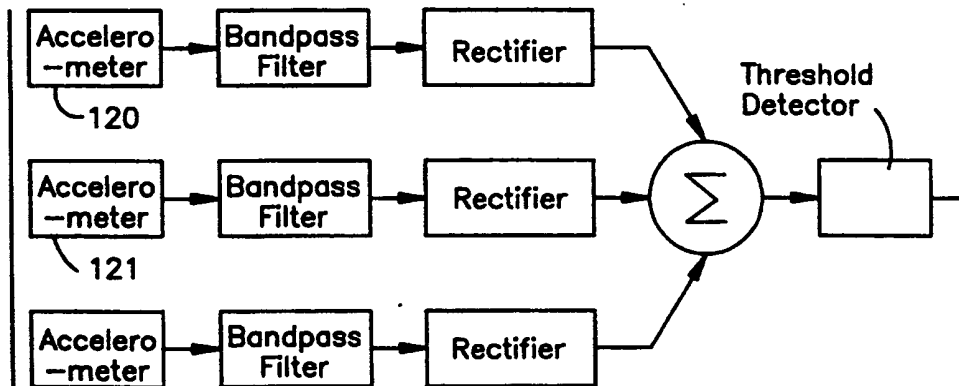
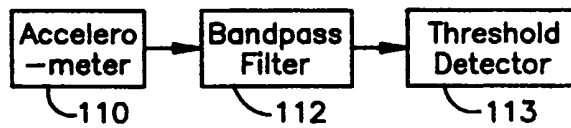


FIG. 11(b)